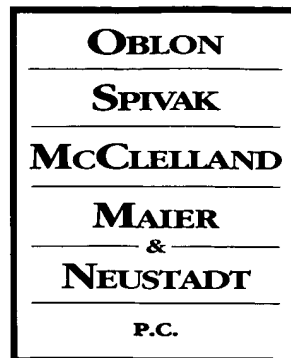


COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

Docket No.: 219928US0



RE: Application Serial No.: 10/078,409
Applicants: Francine BALDO, et al.
Filing Date: February 21, 2002
For: COMPOSITION FOR TOPICAL APPLICATION
COMPRISING AT LEAST ONE
HYDROXYSTILBENE AND AT LEAST ONE
POLYOL TO SOLUBILIZE THE
HYDROXYSTILBENE
Group Art Unit: 1617
Examiner: G. YU

ATTORNEYS AT LAW
RICHARD L. TREANOR
(703) 412-6007
RTREANOR@OBLON.COM

JEFFREY B. MCINTYRE
(703) 413-3000
JMCINTYRE@OBLON.COM
*BAR OTHER THAN VIRGINIA

SIR:

Attached hereto for filing are the following papers:

**Appeal Brief w/Appendices;
Petition for Extension of Time (3 Months).**

Our credit card payment form in the amount of \$1,320.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

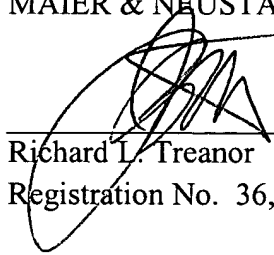
11/30/2004 HTECKLU1 00000112 10078409

01 FC:1402

340.00 DP

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.


Richard L. Treanor
Registration No. 36,379

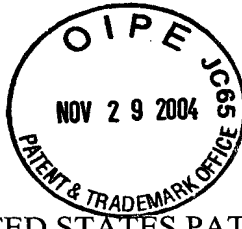
Customer Number

22850

(703) 413-3000 (phone)
(703) 413-2220 (fax)

Jeffrey B. McIntyre
Registration No. 36,867

Docket No. 219928US0



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

:

Francine BALDO, et al.

:

EXAMINER: G. Yu

SERIAL NO: 10/078,409

:

FILED: February 21, 2002

:

GROUP ART UNIT: 1617

FOR: COMPOSITION FOR TOPICAL APPLICATION
COMPRISING AT LEAST ONE HYDROXYSTILBENE
AND AT LEAST ONE POLYOL TO SOLUBILIZE THE
HYDROXYSTILBENE

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Appellants submit this brief in response to the Final Rejection dated January 28, 2004.

REAL PARTY IN INTEREST

The real party in interest herein is L'Oréal S.A. of Paris, France.

RELATED APPEALS AND INTERFERENCES

To the best of Appellants' knowledge, there are no other appeals or interferences which will directly affect or be directly affected by, or have a bearing on, the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1-42 are pending.

STATUS OF AMENDMENTS

All amendments and remarks filed in this case have been entered and considered.

SUMMARY OF INVENTION

The invention relates to compositions containing at least one hydroxystilbene and a hydroxystilbene solubilizing effective amount of at least one polyol (for example, compositions containing polyol and hydroxystilbene in a ratio of at least 150/1). (Specification at Table 10, pages 27-28). The invention composition can be used to treat signs of aging. (Specification at page 31, lines 12-14). Preferably, the invention composition is an oil-in-water emulsion. (Specification at page 7, line 1 et seq.).

The invention also relates to methods of mixing at least one hydroxystilbene with at least one polyol in a weight ratio of polyol to hydroxystilbene of at least 150/1 (specification at page 11, lines 4-6) and of preparing oil-in-water emulsions containing at least one hydroxystilbene and a hydroxystilbene solubilizing effective amount of at least one polyol. (Specification at page 11, line 12 et seq.).

Significantly, the invention composition combines sufficient polyol with hydroxystilbene to solubilize the hydroxystilbene. (Specification at Table 10, pages 27-28).

CONCISE LISTING OF REJECTIONS

1. Whether The Pending Claims Are Obvious Under 35 U.S.C. § 103 Over (1) Pillai (claims 1-9, 14-17, 20-31 and 36-42); and (2) Breton, alone (claims 1-5, 9, 14-17, 20, 23-27, 31 and 36-40) or in combination with Ribier (claims 6, 10-13, 18, 19, 21, 22, 28, 32-35, 41 and 42).

GROUPING OF CLAIMS

The claims do not stand or fall together. Each claim stands individually, and in the argument section provided below Appellants explain why the claims are each separately patentable, one from the other.

ARGUMENT

The invention compositions and methods relate to novel combinations of at least one hydroxystilbene and at least one polyol. In this regard, the specification demonstrates that a significantly high polyol to hydroxystilbene ratio is necessary to effect hydroxystilbene solubilization. (See, specification at pages 27-30). None of the cited art teaches, suggests or recognizes any benefits associated with combining polyols and hydroxystilbenes in such high ratios. In other words, the invention compositions and methods optimize polyol/hydroxystilbene combinations by providing specified, limited polyol/hydroxystilbene ratios which result in effective hydroxystilbene solubilization by polyols. The cited art neither teaches nor suggests this invention.

This invention is significant because, as noted in the specification, hydroxystilbenes have low solubility in cosmetic solvents and, in fact, tend to crystallize in cosmetic compositions. (Specification at page 3, lines 8-11). This crystallization/lack of solubility can hinder the hydroxystilbene's effectiveness/activity and can change the overall stability and/or appearance of the composition. (Specification at page 3, lines 11-15). The invention compositions and methods address such problems by enabling effective hydroxystilbene solubilization.

Initially, Appellants note that the Examiner has basically ignored the claim limitation in claims 23-42 which requires the presence of "a hydroxystilbene solubilizing effective amount" of at least one polyol, asserting that such limitations are significant in method claims, but not in composition claims. (Advisory Action dated August 6, 2004 at page 2). Thus, the Examiner has failed to consider all limitations in claims 23-42 as required. (See, MPEP (Rev'd May 2004) § 2143.03 at page 2100-133). Significantly, the ignored claim limitations relate directly to a major point of novelty for the invention compositions and methods: hydroxystilbene solubilization. Thus, the Examiner has rejected claims 23-42 without considering one of the most significant limitations in these claims. For this reason alone the Examiner's rejection of claims 23-42 is flawed, and should be reversed.

The "effective amount" limitation in claims 23-42 is a real limitation which must be taught or suggested by prior art before a proper prior art rejection can be made: that is, the cited art must teach or suggest solubilizing hydroxystilbene with polyol. See, *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 67 U.S.P.Q.2d 1191 (Fed. Cir. 2003). Neither primary reference (Breton or Pillai) discloses, suggests or

recognizes the significance of polyol's ability to solubilize hydroxystilbene, or the criticality of combining sufficient polyol with hydroxystilbene to achieve such solubilization. In view of Abbott, the cited art cannot render these claims obvious.

Moreover, with respect to all pending claims, the Examiner has asserted that there is no evidence showing "criticality" for the claimed ratios. (Office Action dated January 28, 2004 at page 3). However, criticality does, in fact, exist. This criticality is demonstrated in the examples on pages 27-30 of the specification in which the disclosed compositions having a ratio of 150:1 result in hydroxylstilbene solubilization, but the disclosed compositions having a ratio of 100:1 or less do not. These examples show that compositions having a ratio of 150:1 (claims 1-22) and that compositions having a hydroxystilbene solubilization effective amount of polyol (claims 23-42) lead to hydroxystilbene solubilization, whereas smaller ratios of hydroxystilbene and polyol (such as those disclosed in Breton (10:1) and Pillai (1.5:1)) do not. By themselves, these examples and the criticality of the claimed invention which they demonstrate are sufficient to show that the claimed invention is not obvious, and to overcome the § 103 rejections. For this reason as well the rejections under 35 U.S.C. § 103 are improper and should be reversed.

Finally, Breton's and Pillai's broad, general disclosure concerning the possible combination of a hydroxystilbene and a polyol is insufficient to render obvious the invention compositions and methods which relate to the specific combination of specific hydroxystilbene : polyol ratios.

First, neither Breton nor Pillai recognizes the importance of combining a hydroxystilbene with a polyol. Rather, Breton teaches that moisturizers (of which glycerin

and butylene glycol are examples) could optionally be added to his compositions, (Breton at col. 5, lines 57-58), while Pillai teaches that emollients such as polyols could optionally be added to his compositions. (Pillai at col. 3, lines 58-63). Thus, both Breton and Pillai teach/suggest optionally combining hydroxystilbenes with compounds having moisturizing/emollient properties regardless of what those compounds are (as long as they are moisturizers/emollients). Any moisturizer/emollient would suffice. In other words, neither Breton nor Pillai attaches any significance to specifically combining a hydroxystilbene with a polyol.

Second, neither Breton nor Pillai discloses or suggests combining at least one hydroxystilbene with an amount of polyol sufficient to solubilize the hydroxystilbene. Breton does not disclose concentration ranges for the moisturizers which could optionally be added to his compositions. (See, Breton at col. 5, lines 57-58). Thus, contrary to the Examiner's assertion, Breton does not teach adding a "general range" of 1-7% polyol to his compositions. Rather, Breton's only teaching concerning polyol concentration relates to the relative ratios of hydroxystilbene and polyol provided by the particular ratios of these two compounds in the examples. In these examples, Breton discloses compositions containing polyol and hydroxystilbene in ratios no greater than 10:1. Accordingly, one skilled in the art, seeking to combine polyol with hydroxystilbene in accordance with Breton's disclosure, would not be motivated to create general polyol concentration ranges not disclosed by Breton and then experiment with various combinations within such ranges. Instead, one skilled in the art would follow Breton's disclosure, using at most a 10:1 polyol : hydroxystilbene ratio. Such ratios are insufficient to effect hydroxystilbene solubilization and, thus, cannot render the

claimed invention obvious.

Similarly, Pillai's only teaching concerning polyol concentration relates to the relative ratios of hydroxystilbene and polyol provided by the particular ratios of these two compounds in Pillai's example 5, where the ratio is a mere 1.5:1. Pillai's general disclosure concerning concentration ranges for resveratrol and for emollient are too general to provide guidance concerning the specific combination of hydroxystilbene and polyol being claimed. Moreover, even assuming that one skilled in the art would theoretically be motivated to experiment with Pillai's broad, general ranges, nothing in Pillai would motivate one skilled in the art to focus on a small, specific portion of such ranges to arrive at the specific ratios of the claimed invention.

Ribier cannot compensate for Breton's or Pillai's deficiencies. Ribier does not disclose or suggest compositions containing both a hydroxystilbene and a polyol, nor does Ribier disclose or suggest solublizing hydroxystilbenes with polyols.

In view of the above, Appellants respectfully submit that the present claims are in condition for allowance, and that the pending rejection should be REVERSED.

Each dependent claim similarly points out and describes a patentable invention neither disclosed nor suggested by the applied prior art. These claims themselves are separately patentable.

Claims 2, 3, 24 and 25, each separately patentable, are composition claims further requiring the presence of specific hydroxystilbenes. Nowhere do Breton, Pillai or Ribier describe or allude to these specific hydroxystilbenes as being significant, nor do Breton, Pillai

or Ribier describe or suggest any benefits resulting from the use of such hydroxystilbenes in combination with a hydroxystilbene solubilizing effective amount of polyol.

Claims 4 and 26, each separately patentable, are composition claims further specifying the amount of hydroxystilbene present. Neither Breton, Pillai nor Ribier teaches or suggests compositions having this specific amount of hydroxystilbene present, or any benefits resulting from such compositions.

Claims 5, 6, 27 and 28, each separately patentable, are composition claims further requiring the presence of specific polyols. Nowhere do Breton, Pillai or Ribier describe or allude to these specific polyols as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such polyols in combination with hydroxystilbenes.

Claims 7, 8, 29 and 30, each separately patentable, are composition claims further requiring the presence of at least one C₁-C₆ alkanol. Nowhere does Breton, Pillai or Ribier describe or allude to this additional ingredient of the claimed compositions as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such C₁-C₆ alkanols in the invention compositions.

Claims 9 and 31, each separately patentable, are composition claims further requiring the composition to be an emulsion, a gel or a solution. Nowhere does Breton, Pillai or Ribier describe or allude to this additional characteristic of the claimed compositions as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such compositions.

Claims 10-13 and 32-35, each separately patentable, are composition claims further requiring the composition to be a specific type of oil-in-water emulsion having specific characteristics. Nowhere does Breton, Pillai or Ribier describe or allude to this type of emulsion or the additional characteristics of the emulsion as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such emulsions.

Claims 14, 15, 36 and 37, each separately patentable, are composition claims further requiring the presence of at least one oily phase. Nowhere does Breton, Pillai or Ribier describe or allude to this additional characteristic of the claimed compositions as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such an oily phase in the invention compositions.

Claims 16 and 38, each separately patentable, are composition claims further requiring the presence of specific adjuvants. Nowhere does Breton, Pillai or Ribier describe or allude to these additional ingredients of the claimed compositions as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such an adjuvant.

Claims 17 and 39, each separately patentable, are method claims requiring mixing specific ratios of hydroxystilbene and polyol. Nowhere does Breton, Pillai or Ribier describe or allude to the production of such compositions via such steps, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from such methods.

Claims 18 and 19, each separately patentable, are method claims requiring specific steps for the production of specific types of emulsions. Nowhere does Breton, Pillai or Ribier

describe or allude to the production of such emulsions via such steps, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from such methods.

Claims 20 and 40, each separately patentable, are method claims requiring specific application of the claim 1 and claim 23 compositions, respectively. Neither Breton, Pillai nor Ribier discloses or suggests using the claimed compositions in such methods and, thus, are free of the prior art.

Claims 21 and 41, each separately patentable, are composition claims further requiring the presence of at least one retinoid. Nowhere does Breton, Pillai or Ribier describe or allude to this additional characteristic of the claimed compositions as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such retinoids.

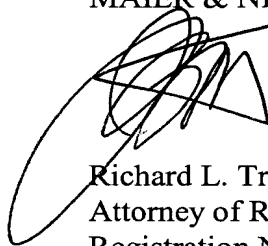
Claims 22 and 42, each separately patentable, are composition claims further requiring the presence of at least one vitamin. Nowhere does Breton, Pillai or Ribier describe or allude to this additional ingredient of the claimed compositions as being significant, nor do Breton, Pillai or Ribier describe or suggest any benefits resulting from the use of such a vitamin.

Application No. 10/078,409
Appeal Brief

Accordingly, in view of the above remarks and reasons explaining the patentable distinctness of the presently appealed claims over the applied prior art, Appellants request that the Examiner's rejections all be REVERSED.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

A handwritten signature in black ink, appearing to be 'R. Treanor', is written over the printed name and title of Richard L. Treanor.

Richard L. Treanor
Attorney of Record
Registration No. 36,379

Jeffrey B. McIntyre
Registration No. 36,867

Customer Number

22850

Tel. #: (703) 413-3000

Fax #: (703) 413-2220



APPENDIX I (CLAIMS)

1. (Original): A composition comprising at least one hydroxystilbene and at least one polyol, wherein the weight ratio of the polyol to the hydroxystilbene is at least 150/1.

2. (Original): The composition according to Claim 1, comprising a hydroxystilbene selected from the group consisting of:

- 4'-hydroxystilbene,
- 2',4'-dihydroxystilbene,
- 3',4'-dihydroxystilbene,
- 4,4'-dihydroxystilbene,
- 2',4',4-trihydroxystilbene,
- 3',4',4-trihydroxystilbene,
- 2,4,4'-trihydroxystilbene,
- 3,4,4'-trihydroxystilbene,
- 3,4',5-trihydroxystilbene,
- 2',3,4-trihydroxystilbene,
- 2,3',4-trihydroxystilbene,
- 2',2,4'-trihydroxystilbene,
- 2,4,4',5-tetrahydroxystilbene,

Application No. 10/078,409
Appeal Brief

- 2',3,4',5-tetrahydroxystilbene,
- 2,2',4,4'-tetrahydroxystilbene,
- 3,3',4',5-tetrahydroxystilbene,
- 2,3',4,4'-tetrahydroxystilbene,
- 3,3',4,4'-tetrahydroxystilbene,
- 3,3',4',5,5'-pentahydroxystilbene,
- 2,2',4,4',6-pentahydroxystilbene,
- 2,3',4,4',6-pentahydroxystilbene, and
- 2,2',4,4',6,6'-hexahydroxystilbene.

3. (Previously Presented): The composition according to Claim 1, wherein the at least one hydroxystilbene is 3,4',5-trihydroxystilbene.

4. (Original): The composition according to Claim 1, wherein at least one hydroxystilbene is present in a quantity of from 0.001% to 10% by weight, with respect to the total weight of the composition.

5. (Original): The composition according to Claim 1, comprising a polyol selected from the group consisting of glycerine, a glycol, polyethylene glycol and their mixtures.

6. (Original): The composition according to Claim 5, comprising a polyol selected

from the group consisting of polyethylene glycol, butylene-1,3-glycol and 5-[2-(4-hydroxyphenyl)vinyl]benzene-1,3-diol.

7. (Original): The composition according to Claim 1, further comprising a C₁-C₆, alkanol.
8. (Original): The composition according to Claim 7, wherein the alkanol represents up to 10% by weight of the total weight of the composition.
9. (Original): The composition according to Claim 1, wherein said composition is in the form of an emulsion of the oil-in-water type or the water-in-oil type, a nanoemulsion, a microemulsion, an aqueous gel, an anhydrous gel, a solution, or a multiple emulsion.
10. (Original): The composition according to Claim 1, wherein said composition is in the form of an oil-in-water emulsion formed of oily globules provided with a lamellar liquid crystal coating dispersed in an aqueous phase.
11. (Original): The composition according to Claim 10, wherein the oily globules have an average diameter of less than 500 nanometers.
12. (Original): The composition according to Claim 10, wherein the lamellar liquid crystal coating is a monolamellar or oligolamellar layer obtained from at least one lipophilic surface-active agent, at least one hydrophilic surface-active agent, and at least one fatty acid.
13. (Original): The composition according to Claim 10, wherein the aqueous phase comprises the hydroxystilbene and the polyol in the dissolved state.

14. (Original): The composition according to Claim 1, further comprising an oily phase, the oily phase comprising an animal, plant, mineral, silicone, fluorinated and/or synthetic oil.

15. (Original): The composition according to Claim 14, wherein the oily phase further comprises at least one fatty alcohol or at least one fatty acid and at least one surface-active agent.

16. (Original): The composition according to Claim 1, further comprising at least one adjuvant selected from the group consisting of preservatives, perfumes, fillers, UV filters, and skin-care agents.

17. (Original): A method comprising mixing at least one hydroxystilbene with at least one polyol in a weight ratio of polyol to hydroxystilbene of at least 150/1.

18. (Previously Presented): A method for the preparation of an oil-in-water emulsion comprising:

-mixing with agitation an oily phase comprising a lipophilic surface-active agent, a hydrophilic surface-active agent and a fatty acid with an aqueous phase comprising a basic agent, a polyol, and a hydroxystilbene, and

- homogenizing the mixture obtained from the first step;

wherein the weight ratio of polyol to hydroxystilbene is at least 150/1.

19. (Original): The method according to Claim 18, wherein homogenization is achieved either using pressures of between 200 and 1000 bars, or by ultrasound, or by use of homogenizers fitted with a rotor-stator head.

20. (Previously Presented): A method, comprising applying the composition of Claim 1 to the skin in an amount effective to treat signs of ageing.

21. (Previously Presented): The composition according to Claim 1, further comprising a retinoid.

22. (Previously Presented): The composition according to Claim 1, further comprising a vitamin.

23. (Previously Presented): A composition comprising at least one hydroxystilbene and a hydroxystilbene solubilizing effective amount of at least one polyol.

24. (Previously Presented): The composition according to Claim 23, comprising a hydroxystilbene selected from the group consisting of:

- 4'-hydroxystilbene,
- 2',4'-dihydroxystilbene,
- 3',4'-dihydroxystilbene,
- 4,4'-dihydroxystilbene,
- 2',4',4-trihydroxystilbene,

Application No. 10/078,409
Appeal Brief

- 3',4',4-trihydroxystilbene,
- 2,4,4'-trihydroxystilbene,
- 3,4,4'-trihydroxystilbene,
- 3,4',5-trihydroxystilbene,
- 2',3,4-trihydroxystilbene,
- 2,3',4-trihydroxystilbene,
- 2',2,4'-trihydroxystilbene,
- 2,4,4',5-tetrahydroxystilbene,
- 2',3,4',5-tetrahydroxystilbene,
- 2,2',4,4'-tetrahydroxystilbene,
- 3,3',4',5-tetrahydroxystilbene,
- 2,3',4,4'-tetrahydroxystilbene,
- 3,3',4,4'-tetrahydroxystilbene,
- 3,3',4',5,5'-pentahydroxystilbene,
- 2,2',4,4',6-pentahydroxystilbene,
- 2,3',4,4',6-pentahydroxystilbene, and

- 2,2',4,4',6,6'-hexahydroxystilbene.

25. (Previously Presented): The composition according to Claim 23, wherein the at least one hydroxystilbene is 3,4',5-trihydroxystilbene.

26. (Previously Presented): The composition according to Claim 23, wherein at least one hydroxystilbene is present in a quantity of from 0.001% to 10% by weight, with respect to the total weight of the composition.

27. (Previously Presented): The composition according to Claim 23, comprising a polyol selected from the group consisting of glycerine, a glycol, polyethylene glycol and their mixtures.

28. (Previously Presented): The composition according to Claim 27, comprising a polyol selected from the group consisting of polyethylene glycol, butylene-1,3-glycol and 5-[2-(4-hydroxyphenyl)vinyl]benzene-1,3-diol.

29. (Previously Presented): The composition according to Claim 23, further comprising a C₁-C₆, alkanol.

30. (Previously Presented): The composition according to Claim 29, wherein the alkanol represents up to 10% by weight of the total weight of the composition.

31. (Previously Presented): The composition according to Claim 23, wherein said composition is in the form of an emulsion of the oil-in-water type or the water-in-oil type, a nanoemulsion, a microemulsion, an aqueous gel, an anhydrous gel, a solution, or a multiple emulsion.

32. (Previously Presented): The composition according to Claim 23, wherein said composition is in the form of an oil-in-water emulsion formed of oily globules provided with a lamellar liquid crystal coating dispersed in an aqueous phase.

33. (Previously Presented): The composition according to Claim 32, wherein the oily globules have an average diameter of less than 500 nanometers.

34. (Previously Presented): The composition according to Claim 32, wherein the lamellar liquid crystal coating is a monolamellar or oligolamellar layer obtained from at least one lipophilic surface-active agent, at least one hydrophilic surface-active agent, and at least one fatty acid.

35. (Previously Presented): The composition according to Claim 32, wherein the aqueous phase comprises the hydroxystilbene and the polyol in the dissolved state.

36. (Previously Presented): The composition according to Claim 23, further comprising an oily phase, the oily phase comprising an animal, plant, mineral, silicone, fluorinated and/or synthetic oil.

37. (Previously Presented): The composition according to Claim 36, wherein the oily phase further comprises at least one fatty alcohol or at least one fatty acid and at least one surface-active agent.

38. (Previously Presented): The composition according to Claim 23, further comprising at least one adjuvant selected from the group consisting of preservatives, perfumes, fillers, UV filters, and skin-care agents.

39. (Previously Presented): A method comprising mixing at least one hydroxystilbene with a hydroxystilbene solubilizing effective amount of at least one polyol.

40. (Previously Presented): A method, comprising applying the composition of Claim 23 to the skin in an amount effective to treat signs of ageing.

41. (Previously Presented): The composition according to Claim 23, further comprising a retinoid.

42. (Previously Presented): The composition according to Claim 23, further comprising a vitamin.

Application No. 10/078,409
Appeal Brief

APPENDIX II (EVIDENCE)

None.